5:00 p.m.

822-5 **Impact of Radiation Dose on Outcomes in Diabetic Patients: Results From the SCRIPPS IV Trial**

Paul S. Teirstein, Jeffrey Moses, Martin Leon, Michael Collins, Roxanna Mehran, Eve Montang, Manuela Neogota, Huan Giap, Ray Lin, Shirish Jani, Stephen Balter, Jack Dalton, Roberto Lipsztein, Matthew J. Price, Prabhakar Tripuraneni, ScrippsClinic Research Foundation, La Jolla, CA, Lennox Hill Hospital, New York, NY

Background: The Scripps IV trial invesitagated the safety and efficacy of 14 Gy vs 17 Gy of gamma intracoronary radiation for the treatment of instent restenosis (ISR). Patients (pts) with diabetes mellitus (DM) are at particularly high risk for developing recurrent ISR and may benefit from the higher dosing regimen.
Methods: 358 patients with native or vein graft ISR ≤ 80 mm in length and diameter between 2.75 and 4 mm were randomized in a double-blind fashion to 14 or 17 Gy at 2mm from the radiation source. Angiography was obtained at 8 months.
Results: Baseline characteristics were equivalent between the 14 Gy and 17 Gy groups for the DM and non-DM pts, except more males in the DM group received 17 Gy. Mean lesion length was 22mm and mean vessel diameter was 0.75mm. At 8 months, DM pts who received 17 Gy had a 57% reduction in MACE (death, MI, or target lesion revascularization, p=0.003), 63% reduction in target lesion revascularization (TLR) (p<0.002), and a 61% reduction in target vessel revascularzation (TVR) (p<0.001) compared to DM pts receiving 14 Gy. In contrast, higher dosing did not significantly impact MACE in the non-DM pts (22.4% vs 16.3%, p=ns). There were no differences in stent thrombosis between treatment groups in DM or non-DM pts.
Conclusions: In diabetics, a dosing regimen of 17 Gy, instead of the recomended 14 Gy, of gamma radiation at 2 mm from the source is safe and results in significantly less MACE, TLR, and TVR at 8 months. Higher dosing of gamma radiation should be considered when treating diabetic pts.

Diabetes	14 Gy (n=50)	17 Gy (n=64)	p value	No Diabetes	14 Gy (n=116)	17 Gy (n=98)	p value
MACE (Death/MI/TLR)	44.0 %	18.8 %	0.003	MACE (Death/MI/TLR)	22.4 %	16.3 %	NS
Death	2.0%	4.7%	NS	Death	0.9%	1.0%	NS
TLR	42.0 %	15.6 %	<0.002	TLR	20.7 %	15.3 %	NS
TVR	48.0 %	18.8 %	<0.001	TVR	26.7 %	23.5 %	NS
MI	2.0%	3.1%	NS	MI	0.9	1.0%	NS
Acute Stent Thrombosis	0%	0%	NS	Acute Stent Thrombosis	0%	0%	
Late Stent Thrombosis	0%	3.1%	NS	Late Stent Thrombosis	1.7%	0%	

5:15 p.m.

822-6 **Restenosis After Sirolimus-Eluting Stent Implantation: Long-Term Evaluation Following Repeat Percutaneous Intervention**

Pedro A. Lemos, Chourmouzios A. Arampatzis, Angela Hoye, Joost Daemen, Francesco Saia, Andrew T L Ong, Georgios Sianos, Jiro Aoki, Pieter C. Smits, Willem J. van der Giessen, Pim de Feyter, Eugenne McFadden, Sjoerd H. Hofma, Ron T. van Domburg, Patrick W. Serruys, Erasmus University Medical Center, Rotterdam, The Netherlands

Background: Restenosis after sirolimus-eluting stent (SES) implantation has been shown to occur in a small but sizeable proportion of cases. Currently, the best management of patients with post-SES restenosis remains undefined.
Study Population: From April 2002, drug-eluting stent implantation has been adopted as the default strategy in our institution, without clinical or anatomical restrictions. During 6 months enrollment, a total of 631 patients received at least one SES. From these, 22 consecutive patients have undergone subsequent repeat percutaneous intervention to treat post-SES restenosis. The long-term outcomes after the re-treatment are reported.
Results: Patients with post-SES restenosis treated with repeat percutaneous intervention were frequently diabetics (46%). Re-treatment was performed after a median time of 204 days from the index procedure. Most patients were re-treated with implantation of another drug-eluting stent at the restenotic site: new SES implantation in 10 patients (46%), and paclitaxel-eluting stent implantation (46%). The remaining 2 patients were treated with plain balloon dilatation and bare stent implantation respectively. After a median follow-up of 131 days, the incidence of death, myocardial infarction, or re-intervention was zero. One-year follow-up will be available at the presentation.**Conclusions:** Percutaneous re-treatment of post-SES restenosis utilizing repeat drug-eluting stent implantation as the strategy of choice appears to be safe and associated with very low incidence of recurrence at medium-term follow-up.

ORAL CONTRIBUTIONS

830

Distal Embolic Protection

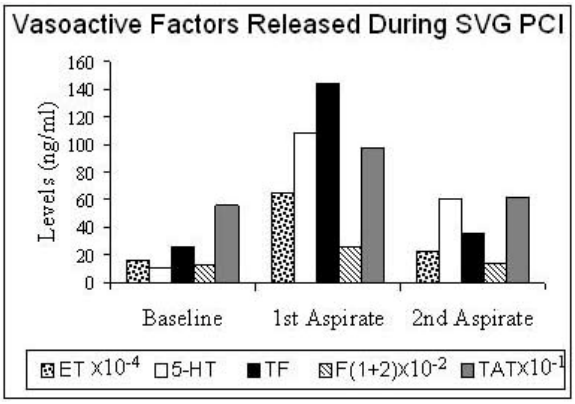
Tuesday, March 09, 2004, 8:30 a.m.-10:00 a.m.
Morial Convention Center, Hall E-1

8:30 a.m.

830-1 **Elimination of Soluble Vasoactive Factors by the PercuSurge GuardWire Distal Protection Device During Percutaneous Coronary Intervention of Saphenous Vein Graft**

Joseph Salloum, Bhagat Reddy, Douglas E. Vaughan, David X. Zhao, Vanderbilt University Medical Center, Nashville, TN

Background: Embolization, vasoconstriction, and *in situ* thrombosis are potential mechanisms of no-reflow during SVG PCI. While most distal protection devices trap debris, only distal occlusion and aspiration systems such as PercuSurge Guardwire (GW) eliminate soluble factors that can lead to vasoconstriction and *in situ* thrombosis. **Methods:** We tested the hypothesis that soluble vasoactive factors were released during PCI and removed by GW in 35 consecutive patients underwent SVG PCI using GW. Blood was taken prior to PCI for baseline measurement of vasoconstrictors: endothelin (ET), serotonin (5-HT), and components of coagulation: tissue factor (TF), plasminogen activator inhibitor 1 (PAI-1), prothrombin fragment 1+2 (F1+2), and thrombin-antithrombin complex (TAT). After stenting and before deflating the distal protection balloon, two aspiration runs were performed with the export catheter and sent for analysis. **Results:** Levels of vasoactive factors were substantially higher in the first post-intervention aspirate as compared to baseline: ET (300% increase, p=0.001), 5-HT (970%, p=0.031), TF (450%, p=0.005), F1+2 (95%, p=0.04), and TAT (76%, p=0.05). Levels were significantly lower in the second aspirate, indicating clearing of these vasoactive factors. **Conclusions:** Vasoactive factors are released during SVG PCI. GW effectively removes debris and soluble factors, which may translate clinically in a more effective distal protection as compared to filter devices.



8:45 a.m.

830-2 **Platelet Glycoprotein IIb/IIIa Receptor Inhibition as Adjunctive Treatment During Saphenous Vein Graft Stenting: Differential Effects After Randomization to Occlusion or Filter-Based Embolic Protection**

Michael Jonas, Gregg W. Stone, James Hermiller, Robert Feldman, Patrick Hall, Robert Haber, Zaki Masud, Patrick Cambier, Ron P. Caputo, Mark Turco, Richard Kovach, Bruce Brodie, Howard C. Hermann, David Cox, Roxana Mehran, Campbell Rogers, Brigham and Women's Hospital, Boston, MA, Cardiovascular Research Foundation, New York, NY

Background: Embolic protection devices (EPD) reduce complications during saphenous vein graft (SVG) PCI. However, periprocedural adverse events occur in >10% of patients. IIb/IIIa inhibitors (IIb/IIIa) have not been proven effective during SVG PCI, although adjunctive use with certain EPD's may improve outcomes.
Methods: In the prospective, multicenter FIRE trial, 651 pts undergoing SVG stenting were randomized to either the FilterWire EX or the balloon occlusion/aspiration GuardWire EPD. IIb/IIIa use was at the discretion of the investigator, but randomization was stratified by intended use. Data regarding IIb/IIIa treatment was available in 646 pts.
Results: In FIRE, IIb/IIIa were used in 345 (51.5%) FilterWire EX and 301 (53.3%) GuardWire pts (p=0.65). Patients preselected for IIb/IIIa use had higher baseline risk: more angina/recent MI (93.9% vs 89.0% p=0.03), lower rate of TIMI 3 flow (77.3% vs 87.1% p=0.001), tighter diameter stenosis (68.6 vs 64.7% p=0.002), and higher SVG degeneration score. They also had a higher incidence of 30d MACE (12.8% vs 8.0% p=0.05).
Although overall success rates and 30d outcomes were similar with both EPD's, marked differences were noted in IIb/IIIa effect between the FilterWire and GuardWire. As opposed to the GuardWire population (MACE with IIbIIIa 15.5%, without IIbIIIa 6.3%

p=0.01) , FilterWire patients treated with IIb/IIIa, despite their high risk profile, had 30d MACE rates (9.9%) similar to their counterparts not on IIb/IIIa (9.5%, p=1.0). In fact, IIb/IIIa in conjunction with FilterWire was associated with a higher rate of successful stent deployment (100% vs 96.8% p=0.02), and a lower incidence of reduced distal flow or ischemia during FilterWire use (3.9% vs 9.6% p=0.05).
Conclusions: 1) Profound platelet inhibition using IIb/IIIa antagonists, in conjunction with distal filter protection devices, may enhance procedural safety and improve late outcomes for high-risk patients during SVG stenting. 2) Further study is warranted to determine how IIb/IIIa inhibition may improve filter function, and allow optimization of filter designs.

9:00 a.m.

830-3 Impact of Vessel Size on Outcomes of Different Distal Protection Devices During Saphenous Vein Graft Intervention: A FIRE Trial Substudy

Aravind Swaminathan, Howard C. Herrmann, Campbell Rogers, James Hermiller, Robert Feldman, Patrick Hall, Robert Haber, A. Masud, Patrick Cambier, Ron P. Caputo, David A. Cox, Ramona Pop, Martin Fahy, Roxana Mehran, Gregg W. Stone, Hospital of the University of Pennsylvania, Philadelphia, PA, The Cardiovascular Research Foundation, New York, NY

Background: In the FIRE trial, distal protection with FilterWire EX (FW) was as effective as GuardWire (GW) in preventing MACE after SVG PCI. The relation between vessel size and MACE with distal protection devices is unknown.
Methods: 651 patients were randomized to FW or GW. The trial inclusion criterion (3.5-5.5 mm) for reference vessel diameter (RVD) was based on visual estimates which were larger than by QCA (median 4.01 vs. 3.31 mm). For this analysis, patients were grouped by tertiles of QCA RVD: <3.04 mm (small), 3.04-3.59 mm (medium), and >3.59 mm (large).
Results: Baseline characteristics were similar, but large vessels were more common in men (p=0.006), less frequent in diabetics (0.008), and more likely to exhibit plaque ulceration (p=0.004) and thrombus (p=0.04). At 30 days, MACE (death, MI (CK-MB>3x nl) and TVR) occurred in 7.0%, 10.1%, 14.8% of pts with small, medium, and large vessels, respectively (p= 0.04). 90% of MACE consisted of peri-procedural MI. MACE stratified by device and QCA vessel size appears in the Table.
Conclusions: In this randomized trial of SVG PCI with distal protection, the incidence of MI and MACE was two-fold higher in large vessels with more complex lesions. MACE rates with the FW, but not GW, were strongly vessel size dependent. FW had a significantly lower MACE rate than GW in small vessels, with no difference in the medium and large vessels. The mechanism and clinical implications of the differential vessel size dependence of distal protection devices requires further study.

Diameter Range (QCA)	FilterWire	GuardWire	Relative Risk [95% CI]	P value
<3.04 mm	3.0% (3/100)	10.9% (11/101)	0.28 (0.08-0.96)	0.05
3.04-3.59 mm	9.1% (10/110)	11.4% (10/88)	0.80 (0.35-1.84)	0.64
>3.59 mm	16.7% (17/102)	12.9% (13/101)	1.29 (0.66-2.52)	0.55
	p=0.003	p=0.85		

9:15 a.m.

830-4 Evaluation of a Distal Protection Filter Device in Patients With Acute Myocardial Infarction: Final Results of the DIPLOMAT Study

Thierry Lefèvre, Philippe Guyon, Bernhard Reimers, Jean-Marie Fauvel, Michel Pansieri, Marie-Pierre Dewez, Institut Cardiovasculaire Paris Sud, Massy, France, Centre Cardiologique du Nord, Saint Denis, France

Background: Primary angioplasty and stenting is now the gold standard in the treatment of acute myocardial infarction (AMI). However, despite a high rate of epicardial flow, myocardial tissue reperfusion remains relatively low as assessed by ST segment resolution. Distal embolization of the thrombotic lesion during PCI could play a major role and this may be improved by distal protection.
Aim of the study: To evaluate the effectiveness of distal protection with the AngioGuard™XP embolic protection device (AG), using a simple and non subjectivean objective and easily measurable marker of myocardial reperfusion: ST segment resolution.
Methods: A prospective, randomized, multicenter study is conducted in 60 pts with AMI < 12 hours. Pts who meet the eligibility criteria are randomized either to the treatment group (PCI combined with AG) or to the control group (PCI only). The primary endpoint is absolute ST segment resolution post-PTCAThe primary endpoint is absolute resolution of the sum of ST segment 1 hour post PCI and secondary endpoints are ST segment resolution >50%, a composite of slow flow, no reflow or distal embolization; regional wall motion index by echocardiography at discharge and 6-month; TIMI frame count post-PCI and ability of the AG to retrieve debris and MACE at 1- and 6-month post-procedure.
Results: 56 pts were randomized to date, both groups were comparable (age 61±12 yrs, diabetes 15%, anterior MI 49%, TIMI flow 0-1 pre PCI 70%). AG was Ssuccessfully placed in all pts in the treatment armment of the Angioguard^{TM} XP was obtained in all the 25 Pts assigned to the treatment group. Debris were captured in 82% of the filters with a diameter of 344±306 μm. Absolute ST segment resolution was 15.8±15.3 mm in the treatment arm vs 9.6±6.7 mm in the control arm (p=0.048). completeST segment resolution was obtained in 80 vs 73 % (p=NS). At 28 days, death occurred in 0 vs 4.2% (p=NS) and death or MI in 3.3 vs 8.3% (p=NS), respectively.
Conclusion: These preliminary results show that the AngioGuard™XP devices effectively and safely captured plaque debris in acute MI. It is associated with improved myocardial reperfusion as assessed by ST segment resolutionM. Complete six-month data will be presented at the meeting.

9:30 a.m.

830-5 The Impact of Myocardial Blush Grade on Clinical Outcomes of Patients Treated With Saphenous Vein Grafts and Thrombotic Native Coronary Arteries: Analysis From the X-TRACT Trial

Yoshihiro Tsuchiya, Alexandra J. Lansky, Ricardo A. Costa, Roxana Mehran, Manuela Negoita, Ecaterina Cristea, Horia Marginean, Maria Corral, Moses Tarawali, Joseph Babb, David A. Cox, Gregg W. Stone, Cardiovascular Research Foundation, New York, NY

Myocardial perfusion (MBG) is a predictor of infarct size, and short- and long-term survival in the setting of acute MI.Whether MBG predicts outcomes following elective PCI in high risk patients with SVG disease or thrombotic native coronary lesions is unknown.
Methods and Results: In the randomized X-TRACT trial, 797 patients underwent PCI to treat diseased SVGs (72.4%) and thrombotic native coronary arteries (27.2%). MBG was analyzed after final intervention and was classified into 3 groups: absent (MBG 0/1) reduced (MBG 2) and normal (MBG 3) perfusion. The final MBG frequency was 69% MBG 3, 21% MBG 2, 10% MBG 0/1, and among the 94% of patients with final TIMI 3 flow MBG 3was achieved in 71% and MBG 0/1 in 8%. Clinical outcomes are shown in the Table.

6 Month Results	MBG 0/1 N=73	MBG 2 N=149	MBG 3 N=491	Overall P-value
Non-QMI, %	35.6	12.5*	15.0 *	<0.0001
Q-MI, %	4.1	1.4	0.8 *	0.07
Death, %	4.1	2.8	1.9	0.44
Death or Any MI %	42.5	15.3*	17.3*	<0.0001
MACE, %	45.2	20.1*	21.6 *	<0.0001
Patients w/ Final TIMI 3	**N=53**	**N=143**	**N=473**	
Death, %	3.8	2.9	1.5	0.37
Death or Any MI,%	28.3	13.7*	16.6*	0.05
MACE,%	32.1	18.7*	21.2	0.04

*P<0.05 vs. MBG 0 /1

There was no significant difference in the outcomes between patients in the MBG 2 and MBG 3 groups.
Conclusions: In patients undergoing elective PCI in high risk lesions, normal myocardial perfusion is achieved in only 71% despite normal epicardial flow. Absent myocardial perfusion is an important prognostic marker of 6 month complications even among patients who achieve normal epicardial flow (TIMI 3).

9:45 a.m.

830-6 Relationship Between Embolic Material Retrieval and Adverse Events With Different Distal Protection Devices During Saphenous Vein Graft Stenting

Giora Weisz, Campbell Rogers, James Hermiller, Robert Feldman, Patrick Hall, Robert Haber, Zaki Masud, Patrick Cambier, Ronald P. Caputo, Mark Turco, Richard Kovach, Bruce Brodie, Howard C. Herrmann, David A. Cox, Roxana Mehran, Gregg W. Stone, Cardiovascular Research Foundation, New York, NY

Background: The high rate of peri-procedural MI in saphenous vein grafts (SVG) stenting is reduced with distal protection devices. Whether retrieval of embolic material (EM) is predictive of adverse events has not been studied.
Methods: In FIRE trial, 651 pts undergoing SVG stenting were randomized to distal protection with FilterWire EX vs. GuardWire balloon occlusion and aspiration system. Based on operators' visual assessment, information whether EM was captured was documented in 610 pts.
Results: EM was captured in 443 pts (73%); 233 (76%) of the FilterWire pts, and 210 (69%) of the GuardWire pts (p=0.12). Demographics, clinical presentation, and lesion characteristics were similar in pts with or without EM captured. Selected procedure characteristics and in-hospital outcomes appear in table. Multivariate analysis revealed that reference vessel diameter and procedure duration, but not capture of embolic material, were independent predictors of MI.
Conclusions: Following SVG stenting, visually evident retrieval of embolic material with the GuardWire, but not with the FilterWire, is associated with a higher rate of peri-procedural MI. Further study is warranted to determine whether this observation reflects incomplete aspiration of embolized material with the GuardWire system, or sub-optimal capture of embolic debris with the FilterWire.